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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/242,700	04/19/1999	NORIKO MIZOBUCHI	20-4518P	1380

2292 7590 07/29/2003

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 07/29/2003

27

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/242,700

Applicant(s)

MIZOBUCHI ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 16 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) 26 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 16, and 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Receipt of Request for Extension of Time and Amendment G received July 7, 2003 is acknowledged. **Claims 14, 16, and 23-25 are pending.** Claims 26-27 are withdrawn from consideration.

Election/Restrictions

Newly submitted claims 26-27 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the originally presented claims are drawn to a composition and newly submitted claim 26 recites a method of treating a malady with an anti-pyretic and claim 27 recites a method of treating neuralgia.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 26-27 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14, 16, and 23-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Instant specification does not support the specific recited percentages in different bases, i.e. a specific percentage in a hydrocarbon gel base and a different percentage in a petrolatum base.. Furthermore applicant does not have examples supporting the new recitation. The specification supports the range of 0.001 to 30, preferably 0.01-20%, and most preferably 0.05-15%. See page 3 of instant specification. However, nowhere in the specification is there support of 20-30% and 25-30% based upon the base. If applicant does have support of the specific weight percentages, applicant is requested to provide specific pages supporting such limitations.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection necessitated by amendments.

In regards to the 112, new matter rejection made in Paper No. 25, the rejection is withdrawn. However, the broadest reasonable definition will be applied to the term "hydrocarbon gel".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14, 16, and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burton et al (4,012,508).

Burton discloses an ointment containing 80 grams acetylsalicylic acid and 2.5 ounces (77 grams) Vaseline. See example 1 in combination with example 10. Burton teaches that generally about 5 to 20 parts by weight of the active is used with 100 parts carrier. Further, Burton teaches manipulating the amount of carrier and active in the composition. For example the amount of the active can be less when the composition is used on diabetics. See column 2, lines 1-10.

Burton does not exemplify the instant weight percent of the aspirin.

It is deemed obvious to one of ordinary skill in the art to look to the teachings of

Burton and manipulate the amount of aspirin in the composition. One would be

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motivated to do so since Burton teaches a general guidance of the amount of aspirin in the composition but teaches that this can be manipulated based on what is desired.

Therefore, one can lessen the amount of active in the composition to if the composition is used on diabetics or increase the amount as in seen in the examples. Generally the differences in concentration will not support patentability of subject matter encompassed by the prior art unless there is evidence indicating that such as concentration is critical.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burton et al (4,012,508) in view of Konishi et al (5,916,918).

Burton discloses an ointment containing 80 grams acetylsalicylic acid and 2.5 ounces (77 grams) Vaseline. See example 1 in combination with example 10. Burton teaches the carrier is any suitable material for topical application and includes oil, creams, and petroleum jellies. See column 1, lines 59-63.

Burton et al does not specify the use of a hydrocarbon gel.

Konishi et al disclose an ointment containing 2g acetylsalicylic acid and 98g plastibase (example 14). The ointment can contain up to 15% aspirin. The reference teaches the use of different bases for ointments such as Vaseline, beeswax, or plastibase (a hydrocarbon gel). Konishi teaches the use of plastibase since it is convenient and commercially available (col. 3, lines 8-11).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Burton et al and Konishi et al and substitute Vaseline with plastibase (a hydrocarbon gel). One would be motivated to do so since Konishi et al teach that Vaseline and plastibase are equivalent ointment bases

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and the only motivation to use plastibase is due to its convenience and commercial availability. Furthermore, Konishi not only teaches the functional equivalence of the components but also teaches the same type of aspirin and ointment composition as Burton et al. Therefore a skilled artisan could reasonably expect success and similar results. Additionally one would expect similar results since both are hydrocarbon bases.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

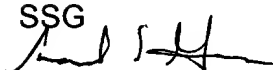
Correspondence

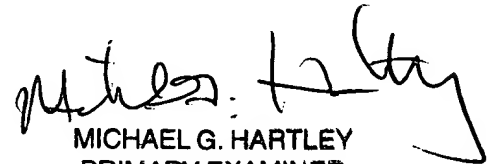
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG

July 25, 2003


MICHAEL G. HARTLEY
PRIMARY EXAMINER